the amendments to the claims and the following discussion, and favorably consider newly presented claims 10-44.

§102 Rejection of Claims 1 - 7

The prior art devices cited by the Examiner have significant dead space areas which allow residual fluid to remain in the device after an injection. Dead space areas are present because the plungers do not conform with the interior contours of the housings. Attachment A contains drawings from the cited references, in which dead-space areas are outlined. Unmarked duplicate copies of the drawings are also provided for reference.

Referring to the Ridderheim '870 patent, Fig. 2 shows a ring-shaped dead-space surrounding the second mating member (86). The profile of the rubber sealing member (44) is not configured to fill the ring-shaped dead space at the end of an injection stroke. Therefore, significant residual fluid is left in the dead space after the injection is completed. In contrast, the plunger in the Applicants' invention is configured to conform to and engage with the interior contour of the housing so that fluid is expelled from the dead space, as recited in Applicants' claim 1. Therefore, Applicants' claim 1 and claims 2-7, which are dependent from claim 1, are not anticipated by the '870 patent.

In the Villen Pascual '133 patent, Figs. 1-2 show a bore at the front end of piston (11). This bore is much larger in diameter than the cutting crown (14) which enters the bore during the injection. The difference in diameter between the bore and the cutting crown creates a ring-shaped dead-space that retains residual fluid after an injection. There is no discernible piston tip that projects from the forward end of the plunger, as recited in Applicants' claim 1. The Applicants' invention includes a piston tip that displaces fluid out of dead space areas. The hollow bore on the end of the plunger in the '133 patent is significantly different from Applicants' piston tip and does not expel fluid from the ring-shaped dead space. As a result, Applicants' claim 1 and claims 2-7, which are dependent from claim 1, are not anticipated by the '133 patent.

In the Gaarde '419 patent, Figs. 1-2 show a tapered piston (14) that engages a substantially flat "yielding" wall (6). When piston (14) engages yielding wall (6), the profile of the piston does not conform with the collapsed wall. As a result, a significant dead-space is created around the tapered piston, as shown in Fig. 2. This dead space retains residual fluid after the needle is retracted. The plunger in Applicants' invention conforms to the shape of the interior wall of the fluid cavity. As a result, Applicants' claim 1 and claims 2-7, which are dependent from claim 1, are not anticipated by the '419 patent.

Double Patenting Rejection

The Examiner rejected claims 8 and 9 under statutory double patenting, in light of U.S. Patent No. 6,096,005 (claims 10, 20,223 and 24). Applicants request that the Examiner reconsider this rejection in light of the differences between claims 8 & 9 and the claims in the and '005 patent.

As set forth in MPEP §804(II)(A), when considering double patenting, the following question should be asked

> Is there an embodiment of the invention that falls within the scope of one claim, but not the other?

If there is such an embodiment, then there is no double patenting.

Among other features recited in claim 10 of the '005 patent is an actuating member having "a central cavity formed therein for receiving the needle." This feature is not recited in claims 8 and 9 of the present application. Therefore, a device that does not have such a cavity may still come within the literal scope of claims 8 and 9, but would not fall within the literal scope of claim 10 of the '005 patent. Therefore, the double patenting rejection of claim 8 & 9 is inappropriate.

With respect to the rejection of claims 8 & 9 over claims 20, 23 and 24 of the '005 patent, Applicants note that the '005 patent only has 18 claims, so Applicants presume the Examiner was referring to another of Applicants' patents. After reviewing Applicants' other patents, it appears that the most likely patent the

Examiner was referring to was U.S. Patent No. 5,407,431. However, the claims of the '431 patent are different from pending claims 8 and 9 so that a double patenting rejection is inappropriate, as discussed below.

Claims 20, 23 and 24 include several features that are not recited in pending claims 8 and 9. For instance, claim 20 is reproduced below with underlining showing some of the features in claim 20 that are not in claims 8 and 9.

> 20. An intravenous catheter insertion device comprising a captured needle received concentrically within a catheter sleeve for insertion of said catheter sleeve along with said insertion needle below a patient's skin, a spring loaded needle means for holding and ejecting sole captured needle, barrel means connectable to said spring loaded needle means on one end, and a plunger means having a hollow portion, said plunger means positionable within and movable through said barrel means, said plunger means having a breakable end adjacent said hollow portion which breaks free from one end of said plunger means and allows said captured needle to be ejected into said hollow portion of said plunger means within said barrel means, wherein said spring loaded needle means has a housing with resilient fingers on one end, which can be spread radially outward by said one end of said plunger means in contact therewith to release said captured needle from said housing, wherein said breakable end of said plunger means breaks allowing said captured needle to be propelled out of said housing and into said hollow portion of said plunger means and be retained therein, wherein said breakable end of said plunger means includes tapered shoulders which engage oppositely and complementing shoulders of said resilient fingers, allowing forward movement of said plunger means to spread said resilient fingers radially outward, said intravenous catheter insertion device further comprising an extending tab and a receiving slot associated between an exterior of said plunger means and the interior of said barrel means,

said extending tab and said receiving slot oriented to lock together when said tab and said slot are brought into alignment with each other within said barrel means, thereby locking said plunger means within said barrel means.

A device that does not have the underlined features may still come within the literal scope of claims 8 and 9, but would not fall within the literal scope of claim 20 of the '005 patent. Therefore, the double patenting rejection of claims 8 & 9 over claim 20 of the '005 patent is inappropriate.

Similarly, claim 23 recites:

23. A retractable needle system comprising:

(a) a catheter sleeve having a flexible shaft with an axial passageway to concentrically receive an insertion needle having a rigid shaft, said rigid shaft having a sharp end and a holder defining an end;

(b) a spring housing having an exterior surface, resilient legs spreadable radially outward on a first end, said spring housing having exteriorly located attachment groove, an opening on a second end of said spring housing to receive said shaft of said insertion needle in sealing engagement while retaining said holder, said resilient legs having radially inwardly positioned hooks sized to engage and hold said end of said holder of said insertion needle when said shaft of said insertion needle is forwardly positioned within said spring housing, said hooks having inwardly tapered shoulders;

(c) a coiled spring means positioned axially within said spring housing between said holder and said second end of said spring housing, said spring means exerting a repulsive force between said holder of said insertion needle and said second end of said spring housing less than the retaining force exerted by said hooks of said resilient legs, thereby retaining said insertion needle within said spring housing against said repulsive force of said spring means;

(d) barrel means for engaging and holding said spring housing, said barrel means including a plurality of ratchet teeth and positioned within an interior of said barrel means to receive said extending groove of said spring housing in locking engagement, said interior of said barrel means shaped sufficient to engage said spring housing and allow said resilient legs to flex radially outward; and

(e) a plunger sized to be received concentrically within said barrel means, said plunger having a hollow axially located chamber therein, and having a dissociable end and outwardly tapered shoulders adjacent to said dissociable end, wherein said dissociable end dissociates from said plunger and is ejected into said chamber when said outward tapered shoulders forcible engage said inwardly tapered shoulders of said hooks of said resilient legs, spreading said resilient legs outwardly and disengaging said hooks from said end of said holder of said insertion needle, thereby allowing said dissociable end to dissociated under a predetermined normal force between said holder of said insertion needle and said dissociable end, and allowing said coiled spring means to eject said insertion needle from said spring housing into said chamber within said plunger.

A device that does not have the underlined features may still come within the literal scope of claims 8 and 9, but would not fall within the literal scope of claim 23 of the '005 patent. Therefore, the double patenting rejection of claims 8 & 9 over claim 23 of the '005 patent is inappropriate.

Finally, claim 24 recites the following:

> 24. An intravenous catheter insertion device comprising a captured needle received concentrically within a catheter sleeve for insertion of said catheter sleeve along with said insertion needle below a patient's skin, a spring loaded needle means for holding and ejecting sole captured needle, barrel means connectable to said spring loaded needle means on one end, and a plunger means having a hollow portion, said plunger means positionable within and movable through said barrel means, said plunger means having an aperture end

adjacent said hollow portion of said plunger means and allows said captured needle to be ejected into said hollow portion of said plunger means within said barrel means, wherein said spring loaded needle means has a housing with resilient fingers on one end, which can be spread radially outward by said one end of said plunger means in contact therewith to release said captured needle from said housing allowing said captured needle to be propelled out of said housing through said aperture end of said plunger means and into said hollow portion of said plunger means and be retained therein, wherein said aperture end of said plunger means includes tapered shoulders which engage oppositely and complementing shoulders of said resilient fingers, allowing forward movement of said plunger means to spread said resilient fingers radially outward, said intravenous catheter insertion device further comprising an extending tab and a receiving slot associated between an exterior of said plunger means and the interior of said barrel means, said extending tab and said receiving slot oriented to lock together when said tab and said slot are brought into alignment with each other within said barrel means, thereby locking said plunger means within said barrel means.

A device that does not have the underlined features may still come within the literal scope of claims 8 and 9, but would not fall within the literal scope of claim 24 of the '005 patent. Therefore, the double patenting rejection of claims 8 & 9 over claim 24 of the '005 patent is inappropriate.

Conclusion

Applicants respectfully request that the Examiner reconsider the rejections in the July 9, 2001 Official Action, and allow claims 1-9. In addition, Applicants requests that the Examiner favorably consider newly presented claims 10-44.

In light of the foregoing, Applicants believe that this application is in form for allowance. The Examiner is encouraged to contact Applicants' undersigned attorney if the Examiner believes that issues remain regarding the allowability of this

application.

Respectfully submitted,

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A Professional Corporation
Attorneys for Applicant(s)

By _____
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PTO Registration No. 41,010

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CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

I hereby certify that this Response and accompanying papers are being deposited on **November 13, 2001** with the United States Postal Service as first-class mail in an envelope properly addressed to COMMISSIONER OF PATENTS AND TRADEMARKS, Washington, DC 20231

November 13, 2001
Date of Certificate

Stephen H. Eland
PTO Registration No. 41,010

Petition for Extension Under 37 CFR §1.136(a)

Applicants' undersigned attorney hereby petitions for an extension of time of 2 months beyond the time period set in the last office communication. The proper fee is enclosed as identified in the enclosed Fee Transmittal form.

November 13, 2001
Date of Certificate

Stephen H. Eland
PTO Registration No. 41,010

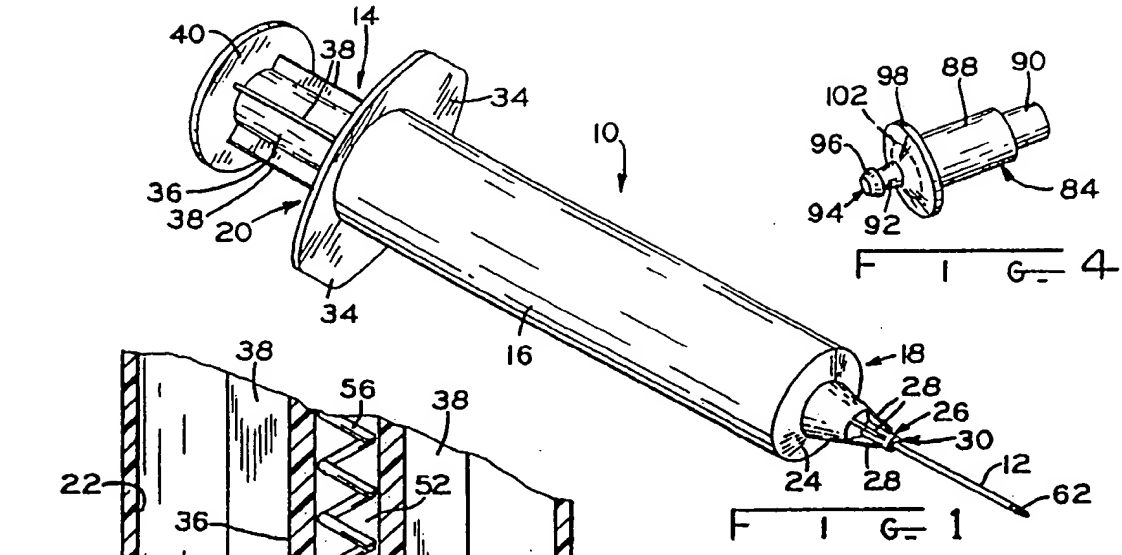

FIG. 1

FIG. 4

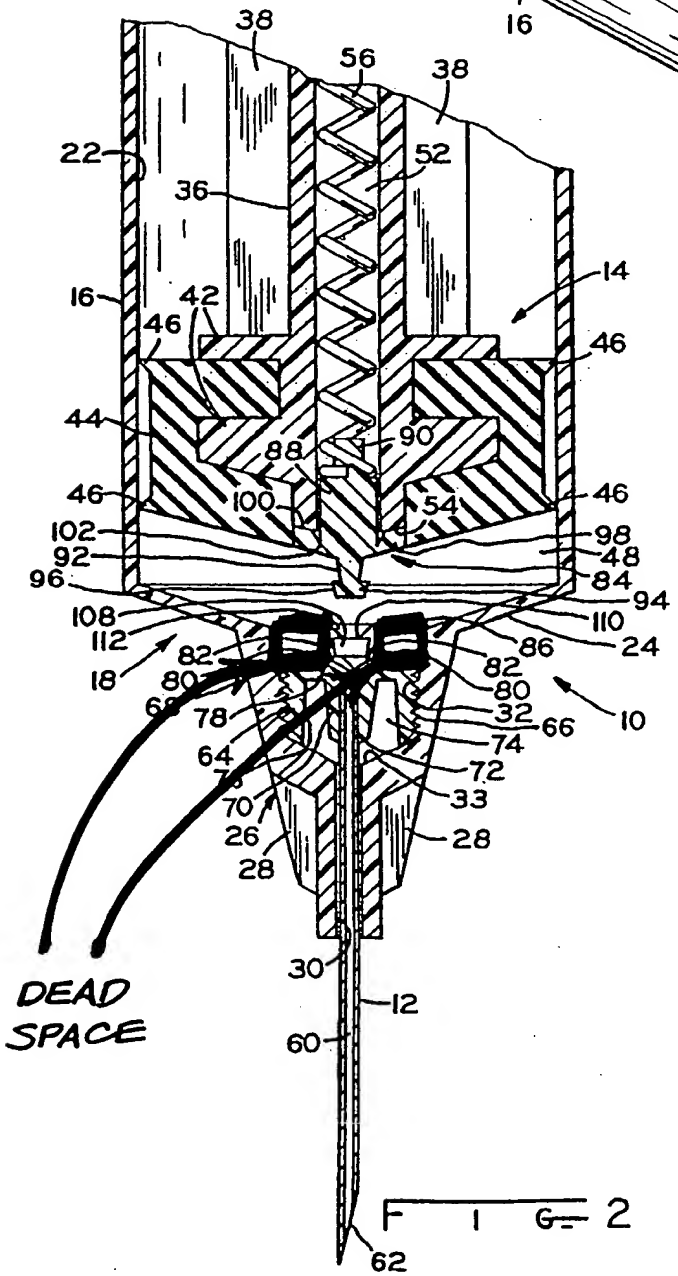

FIG. 2

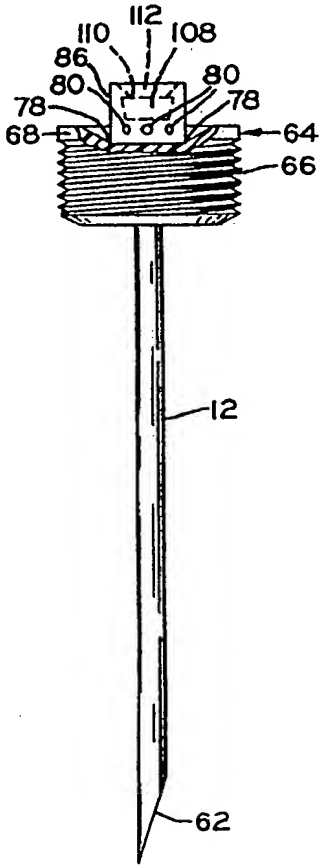

FIG. 3

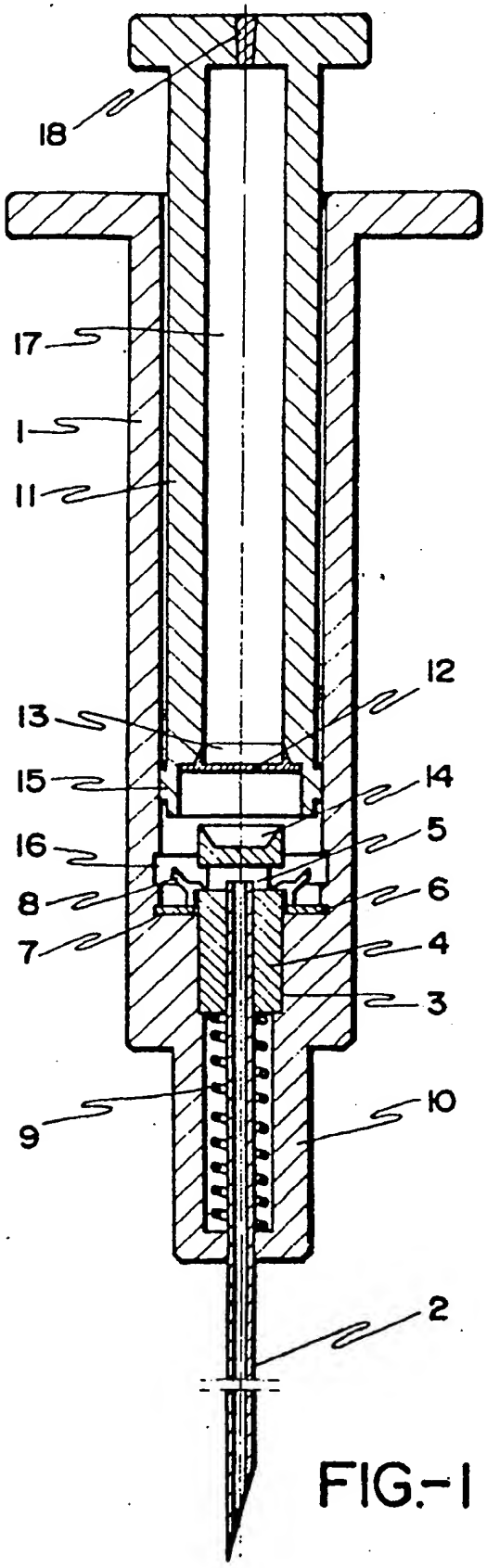
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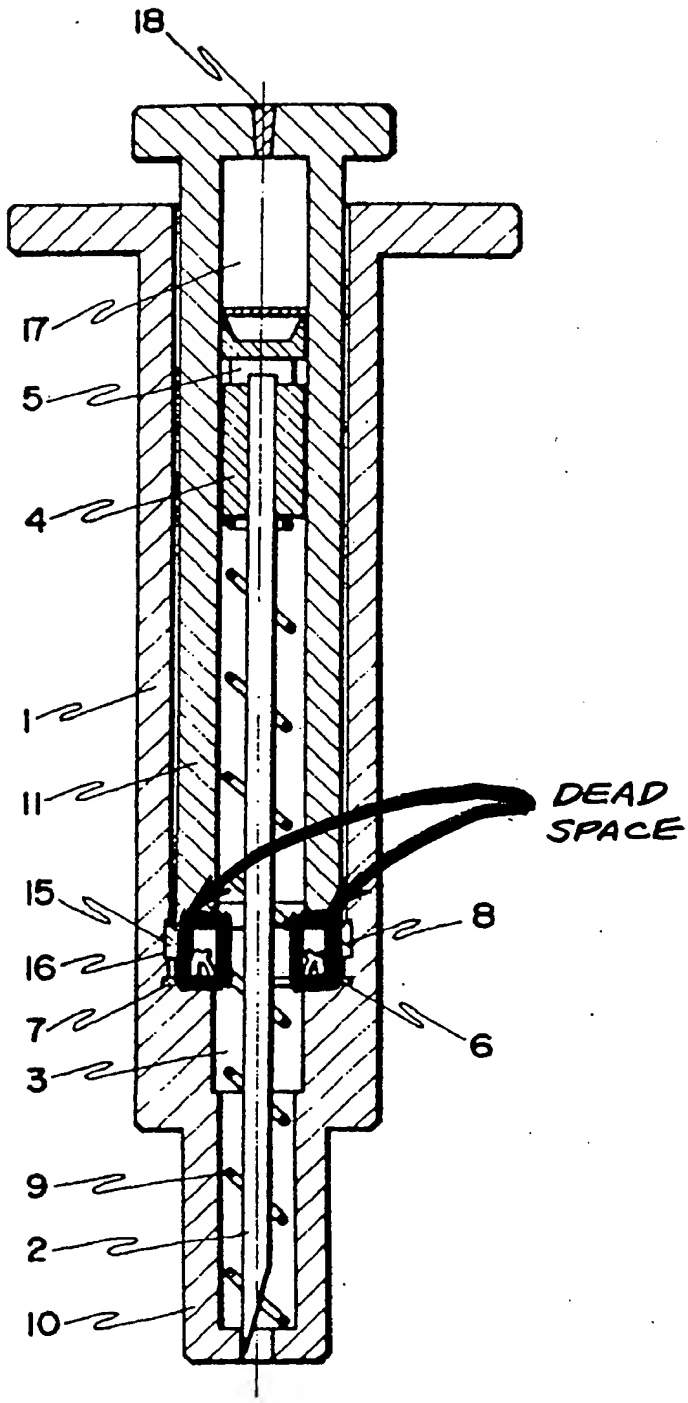
FIG.-1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DEAD SPACE
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FIG.-2

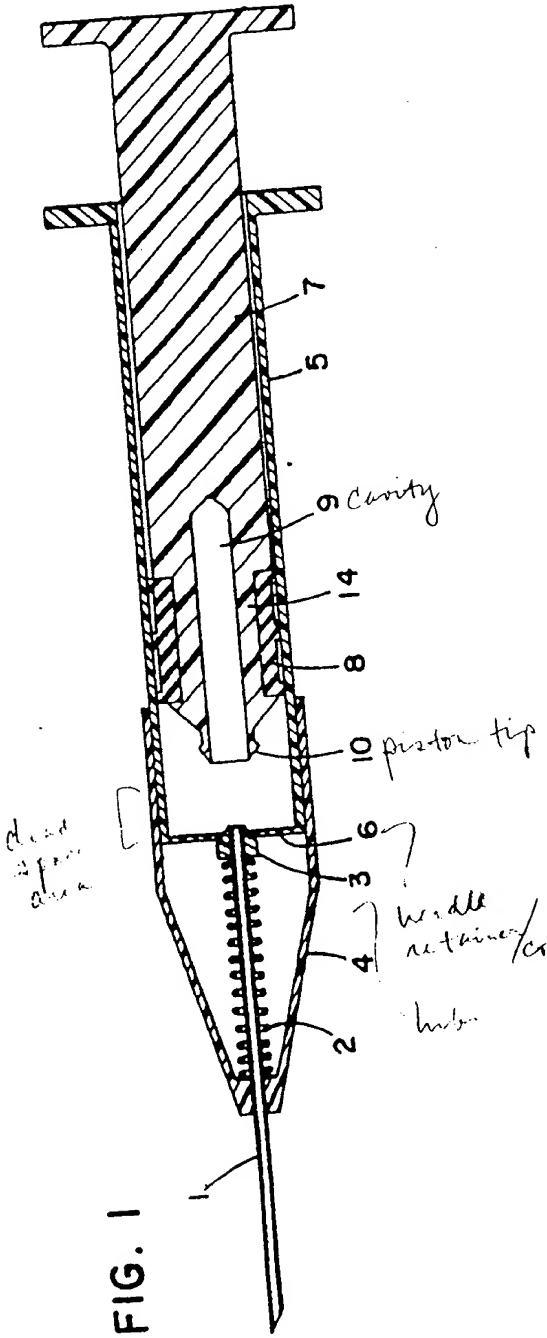

FIG. 1

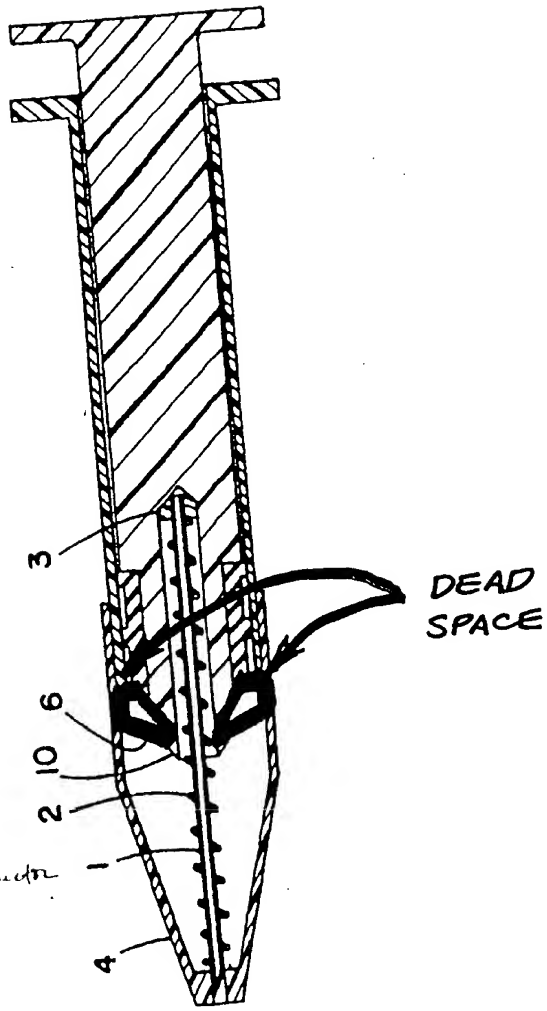

FIG. 2